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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,332	10/26/2005	Ting Liu Carlson	17628.003US1	3516

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EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1781	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,332	CARLSON ET AL.	
	Examiner	Art Unit	
	HAMID R. BADR	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,30 and 32-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-30 and 32-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendment filed 4/28/2010 is acknowledged.

2. Claims 29-30 and 32-49 are being considered on the merits.

Claim Rejections – 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 29-30 and 32-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (US 5,141,858; hereinafter R1) in view of Leathers et al. (US 5,702,942; hereinafter R2).

3. R1 discloses a method for producing oligodextrans for foodstuffs using glucosytransferase of *Leuconostoc mesenteroides (lactic acid bacterium)* strain B-1299. Sucrose is used as the donor molecule and maltose and other sugars as the acceptor molecule. (Abstract and col.2, lines 20 and 26-27).

4. R1 uses maltose as the acceptor molecule. Those of skill in the art know that maltose is a disaccharide composed of two glucose moieties. It is noted that maltose has free hydroxyl groups at positions 2, 3 and 6 which can accept a glucose from sucrose molecule by the action of the enzyme glucosysltransferase. It is also noted that the limitation glucansucrase as presently claimed is a general term for enzymes that

can transfer glucose units from sucrose to acceptor molecules such as maltose. They include glucosyltransferases and dextransucrases.

5. R1 teaches that the highest yields of oligodextrans are obtained when the ratio of concentrations of sucrose to the acceptor molecule (e. g. maltose) is between 0.5 and 10. (Col. 3, line 67 – Col. 4, line 3).

6. R1 discloses that after the synthesis of the oligodextran, the fructose (generated from hydrolysis of sucrose) may be kept in the medium or it may be removed by chromatographic ion exchange method methods. (Col. 4, lines 39-41 and col.11, lines 42-44). It is obvious to one of ordinary skill in the art that a low glycemic index sugar substitute should have reduced assimilable sugars such as fructose and glucose.

7. R1 teaches that the oligodextrans produced by the invention are particularly resistant to enzymatic hydrolysis by glucohydrolase enzymes. This property makes them useful as fillers or extenders in sugar substitutes which are metabolizable by man only slightly on not at all (i.e. low glycemic index material). They may therefore be used in low calorie foodstuff formulations (Col. 2, lines 9-21).

8. R1 is silent regarding the alpha-1,3 and alpha-1,6 linkages in the synthesized product. R1 is also silent regarding the specific strain NRRL B-21297.

9. R2 discloses a mutant of *Leuconostoc mesenteroides* that produces a high proportion of alternan to dextran and a high proportion of alternansucrase to dextransucrase (Abstract).

10. R2 discloses that alternan and alternan derivatives have potential value as non-caloric, carbohydrate based soluble food additives in artificially sweetened foods (Col. 1,

lines 33-35). In addition the valuable sweetener fructose is a by product of the enzymatic synthesis of alternan. (col. 1, lines 36-37)

11. R2 teaches that alternans have alpha-1,3 and alpha-1,6 linkages between constituent glucose units (Fig. 1). It is noted that the alpha-1,3 and alpha-1,6 linkages alternate throughout the molecule.

12. R2 discloses that one of the mutants of *L. mesenteroides* obtained has been assigned the accession number NRRL B-21297 (Col. 9, lines 53-56). This strain is presently being claimed to be the source of the glucansucrase presently claimed.

13. R2 describes the enzymatic production of alternan using alternansucrase and sucrose. (Col. 13, Example 4).

14. While R2 teaches of the specific strain of lactic acid bacteria (NRRL B-21297) in synthesizing alternan from sucrose (i.e. synthesis of a polysaccharides rather than an oligosaccharide), the synthesis of oligosaccharides form sucrose and an acceptor molecule, such as maltose, using alternansucrase was known in the art. Applicants can refer to the Ph. D. dissertation by Cote, G. L. (1983) for details of donor-acceptor reactions using sucrose and maltose and involving alternansucrase. Attention is specifically drawn to Section II (page 52-77) for details of such reactions. On page 77, (second paragraph), Cote clearly discloses the role of the ratio of acceptor to donor and teaches of the type of reaction products produced at higher or lower acceptor to donor molecule. Once this is disclosed in the art, optimizing the acceptor to donor ratio to obtain desired products with specific degrees of polymerization (dp) would be obvious and within the skill of the art.

15. R2 also discloses the desirability of obtaining alternan with a minimum of dextran. (col. 1, lines 48-51). This means that the strain disclosed by R2, has both alternansucrase and dextransucrase, and therefore, it can be substitu

16. The process of synthesizing an oligodextran through the use of a glucosyltransferse (glucansucrase) has been clearly disclosed by R1 using strain B-1299 as the enzyme source. While R1 teaches the glucansucrase reaction using sucrose as the donor and maltose as the acceptor molecules (and very importantly the ratio of donor to acceptor concentration), however, the enzyme source and the conditions employed by R1 will produce oligodextrans having α-1,2 linkages in addition to other products. The synthesis of oligoalternans through the reaction of donor (sucrose) and acceptor (maltose) when alternansucrase is used as the enzyme, with the concomitant production of fructose, was known at the time the invention was made (Applicants are referred to Cote, G. L (1983, Ph.D. dissertation) therefore, the donor (sucrose)-acceptor (maltose) reaction as taught by R1 needed to be modified by employing an alternansucrase source to produce more of the type of oligosaccharides having α.1-3 and α,1-6 linkages as presently claimed. R2 on the other hand discloses strain B-21297 as the source of the enzyme (alternansucrase) and clearly sets forth the advantage of using it to produce more of alternan-type carbohydrates.

17. It is also noted that substituting the strain as taught by R1 with the strain disclosed by R2 will not make the invention of R1 unsatisfactory for its intended purpose, because the strain disclosed by R2 still has the dextransucrase activity

therefore, the alpha, 1-2 bonds will be produced to a lesser extent due to the lower activity of dextransucrase.

18. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to follow the teachings of R1 and make a modification of those teachings by replacing the enzyme source (B-1299) with the enzyme source taught by R2 (B-21297). One would do so to make alternan-type oligosaccharides at a higher concentration. Such carbohydrates are useful as low glycemic, low calorie sweeteners which can be used in food and beverages. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in making low glycemic index carbohydrates.

19. Claims 29-30 and 32-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kossmann et al. (WO 00/47727; hereinafter R3) in view of Leathers et al. (US 5,702,942; hereinafter R2).

3. R3 discloses methods for the preparation of alternan and related products using alternansucrase (glucansucrase) from *Leuconostoc mesenteroids*.

20. R3 discloses the percentage of α,1-3 and α,1-6 linkages in the alternan compounds. (page 4, last paragraph).

21. R3 discloses that in the presence of external acceptors, such as maltose, alternansucrase can catalyze the synthesis of D-glucan chains in which the glucose residues are predominantly alternatingly connected by α,1-3 and α,1-6 bonds and the synthesis of fructose. (page 4 two last lines to page 5; lines 1-3).

22. R3 discloses examples where sucrose or sucrose in the presence of maltose can be used in reactions involving alternansucrase. (page 45, In vitro preparation of alternan by means of protein extracts; page 53, Example 8, Example 9, page 54; Example 11).

23. R3 discloses the ratio of sucrose concentration to maltose concentration in reactions where maltose is used as the acceptor molecule. (Example 2, In vitro preparation of alternan by means of protein extracts).

24. It is noted that the ratio of sucrose concentration to maltose concentration as disclosed by R3 is different from the ratios being presently claimed. However, Applicants can refer to the Ph. D. dissertation by Cote, G. L. (1983) for details of donor-acceptor reactions using sucrose and maltose and involving alternansucrase. Attention is specifically drawn to Section II (page 52-77) for details of such reactions. On page 77, (second paragraph), Cote clearly discloses the role of the ratio of acceptor to donor and teaches of the type of reaction products produced at higher or lower acceptor to donor molecule. Once this is disclosed in the art, optimizing the acceptor to donor ratio to obtain desired products with specific degrees of polymerization (dp) would be obvious and within the skill of the art.

25. While R3 is silent regarding the NRRL B-21297 strain as the source of enzyme, selecting NRRL B-21297 as the enzyme source, because of the production of a high concentration of alternansucrase, would have been obvious to an artisan.

26. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to follow the teachings of R3 and substitute the alternansucrase enzyme of R3 with the enzyme source of R2. One would do so to

utilize a mutant producing a high concentration of alternansucrase for the production of low calorie sweeteners. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in making low glycemic index carbohydrates.

Response to Arguments

Applicants' arguments have been thoroughly reviewed. These arguments are not deemed persuasive.

1. Applicants argue that modification of Paul (R1), as proposed by the Examiner, would render it unsatisfactory for its intended purpose, and that the purpose of Paul is to make alpha, 1-2 bonds.

a. As discussed under rejection sections above, the strain disclosed by R2 has both activities i.e. alternansucrase and dextransucrase. Therefore, modifying R1 by replacing the strain with the strain disclosed by R2 (B-21297) would still produce alpha, 1-2 bonds in the products to a lesser extent. The motivation is clearly disclosed in R2 at col. 1, lines 48-51).

Therefore, the modification as proposed by the Examiner will not make the invention of R1 unsatisfactory for its intended use.

2. Applicants argue that the purpose of Leathers is to select strains which produce high levels of alternan to dextran and have more alternansucrase than dextransucrase.

a. The rejection of claims is an obviousness type rejection and the references are not supposed to be judged on their own. The donor-acceptor type rejections are disclosed by R1. R2 discloses the strains as presently claimed. Therefore, replacing the

strain of R1 with that of R2 would be obvious. The motivation is set forth in R2 for producing more of the alternan-type carbohydrates.

b. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

However, note that while R2 does not disclose all the features of the present claimed invention, R2 is used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention. The bioconversion of sucrose to alternan and alternanoligosaccharides using maltose as the acceptor molecule was known at the time the invention, by the Applicants, was made (please see R2 for making alternan and R3 for maKing alternanoligosaccharides.) Therefore, selecting an enzyme source having a predominant alternansucrase activity, for producing more of the alternan type oligosaccharides , would have been obvious to an artisan.

3. Applicants argue that R3 discloses a ratio of donor to acceptor in Example 2 and that this ratio is different from what is being claimed.

a. It is agreed that the ratio as disclosed by R3 is different from the presently claimed ratio. However, the role of the ratio of donor to acceptor in the donor-acceptor reactions was known in the art. As noted above, rejection section, Cole (1983) clearly discloses the role of the ratios of donor and acceptor molecules and teaches of changing this ratio for making various products having various degrees of polymerization (dp). Any manipulation of that ratio, for producing various products, would have been within the skill of the art.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R. Badr
Examiner
Art Unit 1781

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1781